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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/506,430	02/17/00	GREEN	L 15542-002310

HM12/0808
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER, 8TH FLOOR
SAN FRANCISCO CA 94111

EXAMINER	
LUKTON, D	
ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 08/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/506,430	Green
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 24, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-42* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *18-42* _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

18) ☐ Interview Summary (PTO-413) Paper No(s) _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the peptide TAEEK (page 18)

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

Pursuant to the directives of paper No. 12 (filed 5/24/01), claim 18 has been amended. Claims 18-42 remain pending. In view of applicants' amendment of the claims, a revised restriction is imposed. First however, the following subgenera are defined:

G1 - G6: as defined previously (paper No. 3, mailed 5/24/00);

G7: one (and only one) of R' and R" is an amide;

G8: both of R' and R" is an amide.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121 (The numbering of groups begins with 8, in order to avoid conflict with previously defined groups):

8. Claims 18, 19, 21, 22, 28-35, 39, drawn to a method of inhibiting neovascularization by administering a compound recited in claim 18, with the proviso that G8 is excluded.

9. Claims 18, 19, 21, 22, 28-35, 39, drawn to a method of inhibiting neovascularization by administering a compound recited in claim 18, with the proviso that G7 is excluded.

10. Claims 23, 40-42, drawn to a method of treating diseases by administering a compound recited in claim 18, with the proviso that G8 is excluded.

11. Claims 23, 40-42, drawn to a method of treating diseases by administering a compound recited in claim 18, with the proviso that G7 is excluded.

12. Claims 24-27, drawn to a method of treating diseases by administering a compound recited in claim 18, with the proviso that G8 is excluded.

13. Claims 24-27, drawn to a method of treating diseases by administering a compound recited in claim 18, with the proviso that G7 is excluded.

12. Claims 36-38, drawn to a method of treating diseases by administering a compound recited in claim 18, with the proviso that G8 is excluded.

13. Claims 36-38, drawn to a method of treating diseases by administering a compound

recited in claim 18, with the proviso that G7 is excluded.

Claim 20 will be joined with the elected group.

The claimed inventions are distinct.

Claim 18 has been bisected into two groups, one which includes those embodiments wherein only one of R' and R" is an amide, and a second group which includes those embodiments wherein both of R' and R" is an amide. Claim 18 encompasses the use of peptides which contain 20 amino acids or more. Moreover, the search is not necessarily limited to those references which contain the term "neovascularization". For example, various peptides and proteins have been shown, or proposed to be involved in angiogenesis, e.g., vascular endothelial growth factor, platelet derived growth factor (PDGF), transforming growth factor-*beta*, fibroblast growth factor, matrix metalloproteinases (e.g., collagen, stromelysin, gelatinase). Thus, the search would have to include inhibitors (or antagonists) of each peptide or protein that has been implicated in angiogenesis. In addition, PDGF is released by thrombin; accordingly, an argument could be made that thrombin inhibitors will be effective to inhibit angiogenesis.

Each of claims 23-27, 36-38, and 40-42 recite the following:

"the method of claim 18, wherein the condition is..."

However, the phrase "the condition" lacks antecedent basis. Accordingly, none of claims 23-27, 36-38, and 40-42 is actually subgeneric to claim 18, in spite of the recited claim

dependence. It is noted, however, that each of claims 40 and 41 encompass neovascularization disorders. It is suggested that a new claim be created which is limited to these neovascularization disorders. In the event that this new claim is unequivocally subgeneric to claim 18, and in the further event that applicants have elected either of Groups 8 or 9, the claim thus created may be examined in part. As for the other diseases/disorders, these are distinct from neovascularization. It may well be the case that neovascularization accompanies the growth of tumors. However, if a (prior art) reference were to teach that one of the compounds of claim 18 is effective to inhibit growth of tumors, applicants would likely argue that such a reference does not render claim 18 obvious. Given this argument (that applicants would probably make), the various diseases recited are distinct from neovascularization.

Inventions {12, 13} and {8, 9} are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed. The compounds of claim 18 can be used to inhibit neovascularization in the absence of a vasoactive drug, or chemotherapeutic agent. However, in the event that applicants elect either of Groups 8 or 9, and claims therein found allowable, claims 36-38 will be joined therewith, but subject to the same limitations on the

structure of the "Glu-Trp" compounds.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

Applicants' previous specie elections of pGlu-Trp as the compound, and malignant tumor as the disease will remain in force, absent any request to the contrary by applicants.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1800